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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Technical Specifications for Common
Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Act (at 42 U.S.C. 299b-23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008: 73 FR 70731-70814. AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow health care providers to voluntarily collect and submit standardized information regarding patient safety events. In order to support the Common Formats, AHRQ has provided technical specifications to promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. More information on the Common Formats, including the technical specifications, can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.GOV/index.html>.

The purpose of this notice is to announce a meeting to discuss the Common Formats technical specifications. This meeting is designed as an interactive forum where PSOs and software developers can provide input on these technical specifications. AHRQ especially requests input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the formats electronically.

DATES: The meeting will be held from 8:30 a.m. to 4:00 p.m. on Friday, April 26, 2013.

ADDRESSES: The meeting will be held at the John M. Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: PSO@AHRQ.HHS.GOV.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Disability Management at (301) 827-4840, no later than April 10, 2013.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs – called "patient safety work product" – is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Rule.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. Both the Patient Safety Act and Patient Safety Rule, including any relevant guidance, can be accessed electronically at: <http://www.PSO.AHRQ.GOV/REGULATIONS/REGULATIONS.htm>

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for two settings of care – acute care hospitals and skilled nursing facilities – in order to facilitate standardized data collection. The term "Common Formats" refers to the common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events. AHRQ's Common Formats include:

- Event descriptions (descriptions of patient safety events and unsafe conditions to be reported),
- Specifications for patient safety aggregate reports and individual event summaries,
- Delineation of data elements to be collected for different types of events to populate the reports,
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

AHRQ convenes the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the Department of Health and Human Services (HHS)—the Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the Department of Defense and Department of Veterans Affairs.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment.

Through a contract with AHRQ, NQF solicits feedback on the beta (and subsequent) versions of the Common Formats from private sector organizations and individuals. The NQF, a nonprofit organization that focuses on health care quality, then convenes an expert panel to review the comments received and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revises the Common Formats.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning.

The technical specifications also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Most recently, AHRQ and the PSWG announced the release of Common Formats - Hospital Version 1.2 in the Federal Register on April 13, 2012: 77 FR 22322-22324. The Common Format--Readmissions Version 0.1 Beta for analysis of the circumstances surrounding readmissions into acute care hospitals was announced in the Federal Register on July 20, 2012: 77 FR 42736-42737.

The Software Developer's meeting will focus on discussion of the implementation and use of Hospital Common Formats 1.1 and 1.2; the technical specifications, which provide direction to software developers that plan to implement the Common Formats electronically; and future development plans for the Common Formats. The technical specifications are a critical component that allow for the aggregation of patient safety event data.

The technical specifications consist of the following:

- o data dictionary – defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;

- o clinical document architecture (CDA) implementation guide – provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSO PPC using the Common Formats;

- o validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSO PPC;

- o Common Formats flow charts – diagrams the valid paths to complete generic and event specific formats (a complete event report);

- o local specifications – provides specifications for processing, linking and reporting on events and details specifications for reports; and

- o metadata registry – includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data

elements used by other Federal agencies and standards development organizations [e.g., HL -7, International Standards Organization (ISO)].

Agenda, Registration and Other Information About the Meeting

On Friday, April 26, 2013, a pre-meeting seminar will convene at 8:30 a.m. with focus on data submission, including discussion of technical specifications and aggregate reports. Then, the general meeting will start at 10:00 a.m. with an overview of Federal efforts related to the Common Formats. The agenda will continue with presentations and discussion of implementations of Hospital Common Formats Version 1.1 and 1.2 and next steps for upcoming Common Formats releases. AHRQ staff and contractors will also review database functionality, which is available through the PSO PPC, for PSOs to generate aggregate reports with technical specifications. Finally, the meeting will review data submission both by PSOs and by vendors on behalf of a PSO. Throughout the meeting there will be interactive discussion to allow meeting participants not only to provide input, but also to respond to the input provided by others. A more specific agenda will be provided to meeting registrants before the meeting.

AHRQ requests that interested persons register with the PSO PPC to participate in the meeting. The contact at the PSO PPC is Mark Baliff who can be reached by telephone at (866) 571-7712 and by e-mail at SUPPORT@PSOPPC.ORG. Additional logistical information for the meeting is also available from the PSO PPC. The meeting space will accommodate approximately 150 participants. Interested persons are encouraged to register as soon as possible for the meeting. Non-registered individuals will be able to attend the meeting in person if space is available.

Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats. The formats can be accessed through AHRQ's PSO Web site at <http://www.pso.AHRQ.GOV/formats/commonfmt.htm>. AHRQ is committed to continuing refinement of the Common Formats, and welcomes questions from prospective meeting participants and interested individuals on the technical specifications. These questions should be e-mailed to SUPPORT@PSOPPC.ORG no later than April 10th, 2013. AHRQ will use the input received at this meeting to further update and refine the Common Formats.

Dated: FEB -7 2013

Carolyn M. Clancy, M.D.
Director